

b.) Remarks

Claim 1 has been amended in order to recite the present invention with the specificity required by statute and claims 19 and 21 are amended to correct word processing errors. Additionally, claims 14, 26 and 27 are cancelled and new claims 80-87 are presented in order to more specifically recite various preferred embodiments of the present invention. Claims 15, 18, 19, 21, 23, 24, 56, 57 and 72 are amended to correct their dependency. No new matter has been added.

The Examiner has objected to the drawings as stated on the Notice of Draftsperson's Patent Drawing Review. In response, corrected formal drawings were filed on March 31, 2006 together with a Petition for Extension of Time.

Claims 1, 14, 15, 18-24, 26, 27, 72, 74 and 75 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner questions what is meant by "culturing under non aggregation conditions". In response, that term has been amended to read without forming an embryoid body in conformity with specification page 38, lines 22-27.

At page 3 of the Office Action, the Examiner notes Applicants:

argue[d] addition of BMP-4 was only optional, however the claims did not say optional and because it was an elected species it was considered to be part of the elected invention as a specific factor to be added. Further, it is noted that the claims that specifically recite the addition of other features have been cancelled, and only the embodiment of culturing with stromal cells is present in the claims and no additional "optional" steps are provided in the present claim set.

In response, Applicants respectfully wish to clarify that BMP-4 is not “optional” in the species selected for search but was optional in the independent claims which did not explicitly recite such feature. Nonetheless, solely in order to reduce the issues and expedite prosecution herein, claim 1 has been amended to recite culturing in the presence of BMP-4.

Claims 1, 14, 15, 18-24, 26, 27, 72, 74 and 75 are rejected under 35 U.S.C. §112, first paragraph, because the Examiner contends the specification does not reasonably enable (i) use of stromal cells generally, nor providing (ii) a neural stem cell or¹ (iii) a nerve cell. In response, claim 1 has been amended to specify that a neural crest cell or neural tube cell is produced by differentiating an embryonic stem cell into an ectodermal cell, and subsequently culturing the ectodermal cell. As to the comment that use of stromal cells generally is not enabled, such is not well-understood. Applicants have not stated and do not contend there is anything particularly special or required concerning MC3T3-G2/PA6 stromal cells. If the Examiner is aware of contrary knowledge, then he is respectfully requested to provide an Examiner’s Affidavit under MPEP 2144.03 in the next Patent Office communication.

The Examiner also states it is necessary to deposit MC3T3-G2/PA6 and to aver compliance with the terms of the Budapest Treaty for the same. Aside from the fact that (i) such is commercially available from the RIKEN BioResource Center (see product data sheet attached at Tab.A), Applicants further wish to point out (ii) they already averred to the availability of the KM1310-producing hybridoma cell line deposited as FERM BP-

¹ This subject matter is recited in new claim 81, which also recites that the neural stem cell is stained by anti-nestin antibody.

7573 (see specification page 120, line 34 to page 121, line 4) in their July 16, 2003

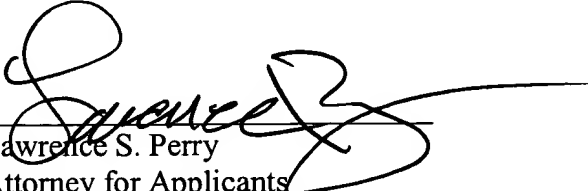
Amendment. A copy of that Declaration is attached at Tab B

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1, 15, 18-24, 56, 57, 72 and 74-87 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,


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CELL SEARCH SYSTEM

[培地・試薬一覧](#)・[細胞データ項目の読み方](#)・[略語一覧](#)

RCB1127 : MC3T3-G2/PA6	
特性(英)	Support hemopoietic stem cell and osteoclast differentiation. Pre-adipocyte.
特性(日)	脂肪細胞に分化する。IL-7を産生しない。造血幹細胞の増殖・分化を支持し、破骨細胞の分化も支持する。
動物種	mouse, C57BL/6
性別	Unknown
年齢	0 day
組織	newborn, calvaria
形態	fibroblast-like
培地	MEM ALPHA+10%FBS
抗生物質	Free
培養最適温度	37°C
CO ₂ 濃度(%)	5%
継代方法	0.25% trypsin
継代頻度	once/week
クローニング有無	No
細胞寿命	infinite
マイコプラズマ	-
アインザイム	LD, NP
樹立者	Kodama, Hiroaki
寄託者	Kodama, Hiroaki
使用条件(英) <small>Used Conditions</small>	No restriction
使用条件(日)	使用制限なし
Reference(英)	1846 1847
利用者成果(英)	2274 2925

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RIKEN BioResource Center
The Institute of Physical and Chemical Research

B R C

00766.000044

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
YOSHIKI SASAI, ET AL.)	Examiner: Thaiann Ton
Application No.: 09/855,587)	Group Art Unit: 1632
Filed: May 16, 2001)	
For: NOVEL DIFFERENTIATION)	
INDUCING PROCESS OF)	
PROCESS OF EMBRYONIC STEM)	
CELL TO ECTODERMAL CELL)	
AND ITS USE)	

Commissioner for Patents
Washington, D.C. 20231

NOTICE RE DEPOSIT OF MICROORGANISMS

Sir:

The above-identified application discloses a cell line which has been deposited with the National Institute of Advance Industrial Science and Technology under the following designation:

Accession Number: FERM BP-7573

The deposit has been made with the National Institute of Advance Industrial Science and Technology under the terms and conditions of the Budapest Treaty. A copy of the International Receipt form is attached. Access to the deposit will be accorded to the Assistant Commissioner upon request and any restrictions upon availability to the public will be irrevocably removed upon granting of any patent issuing on this application or any continuation, divisional or continuation-in-part applications. Maintenance of the deposit is assured for periods of time as specified in the Budapest Treaty.

Kyowa Hakko Kogyo Co., Ltd. will replace the cultures if any should become non-viable for a period of at least five (5) years after the most recent request for

the furnishing of a sample of deposited microorganism, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of such patent, whichever is longer.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: Tadashi Hirata
Tadashi Hirata, President
Date: March 24, 2003

NY_MAIN 330791v1

特許手続上の微生物の寄託の国際的承認
に関するブダペスト条約

下記国際寄託当局によって規則 7. 1 に従い
発行される。

原寄託についての受託証

氏名 (名称) 協和醗酵工業株式会社
取締役社長 平田 正 殿
寄託者 あて名 〒
東京都千代田区大手町一丁目 6 番 1 号

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF
MICROORGANISMS FOR THE PURPOSES OF
PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL
DEPOSIT

issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this
page.

1. 微生物の表示	
(寄託者が付した鑑別のための表示) KM1310	(受託番号) FERM BP- 7573
2. 科学的性質及び分類学上の位置	
1 欄の微生物には、次の事項を記載した文書が添付されていた。 ■ 科学的性質 ■ 分類学上の位置	
3. 受領及び受託	
本国際寄託当局は、平成 13 年 4 月 27 日 (原寄託日) に受領した 1 欄の微生物を受託する。	
4. 移管請求の受領	
本国際寄託当局は、 年 月 日 (原寄託日) に 1 欄の微生物を受領した。 そして、 年 月 日 に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。	
5. 国際寄託当局	
独立行政法人産業技術総合研究所 特許生物寄託センター International Patent Organism Depository 名 称: National Institute of Advanced Industrial Science and Technology センター長 小松 泰彦 Dr. Yasuhiko Komatsu, Director あて名: 日本国茨城県つくば市東 1 丁目 1 番地 1 中央第 6 (郵便番号 305-8566) AIST Tsukuba Central 6.1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan 平成 13 年 (2001) 4 月 27 日	